UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,778	04/14/2004	James Samsoondar	026806-00014	4689

4372   7590   01/04/2010
ARENT FOX LLP
1050 CONNECTICUT AVENUE, N.W.
SUITE 400
WASHINGTON, DC 20036

EXAMINER
SODERQUIST, ARLEN

ART UNIT	PAPER NUMBER
1797	

NOTIFICATION DATE	DELIVERY MODE
01/04/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DCIPDocket@arentfox.com
IPMatters@arentfox.com
Patent_Mail@arentfox.com

PTOL-90A (Rev. 04/07)

	Application No.	Applicant(s)
Office Action Summary	10/823,778	SAMSOONDAR, JAMES
	Examiner	Art Unit
	Arlen Soderquist	1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2009*.

2a)☒ This action is **FINAL**.   2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13-21 and 23-33* is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,13-21 and 23-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All   b)☐ Some * c)☒ None of:

      1.☒ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____ .

1.   The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2.   Claims 1, 3-11, 13-21 and 23-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has added that the sample slot and the sample tab are rectangularly-shaped in transverse cross section. However, applicant did not point to any basis in either the specification or the drawings for the basis of this language. Looking in particular at figures 4a and 5a which show the device, it is clear that the sample tabs (442,542) do not go into a slot (440,540) having a rectangular transverse cross section. Figure 6, while showing structure that appears to show a transverse rectangular cross section is taught in the brief description of the figures as showing more details of the apparatus of the invention shown in figure 5. Thus figure 6 is just different views of the apparatus shown in figure 5a. Likewise it is not clear where the transverse rectangular cross section is shown or described in the description for the tab. For these reasons examiner will treat the rectangularly-shaped limitation as met if a portion of the slot can be said to have a transverse rectangular cross section.

3.   Claims 1, 3-11, 13-21 and 23-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the independent claims requires a sample slot to receive a sample tab. While the slot is defined to have a rectangularly-shaped cross section, it is not clear what if any structural relationship exists between the sample tab and the slot. For example, since the sample tab is not a positively recited element of the apparatus in most of the claims, the shape of the sample tab does not place any limitation on the apparatus of any claims except claims 31-33 where it is positively recited as a claim element. However, since there is no size requirement for the slot any size meets the claim requirements. Does it require the slot to be sized to only fit a sample tab or can a slot of any shape or size be acceptable as long as the sample tab can be placed in the light path within the sample slot? For examination purposes,

examiner will treat the instant language as a slot of any size or shape in which a sample tab can

be placed in the light path as long as a portion of the slot can be said to have a transverse

rectangular cross section as noted above.

4.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in
> section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are
> such that the subject matter as a whole would have been obvious at the time the invention was made to a person
> having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the
> manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459

(1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1.   Determining the scope and contents of the prior art.
2.   Ascertaining the differences between the prior art and the claims at issue.
3.   Resolving the level of ordinary skill in the pertinent art.
4.   Considering objective evidence present in the application indicating obviousness
        or nonobviousness.

5.   Claims 1, 3-11, 13-21 and 23-33 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Jacobs (US 5,846,492) in view of Kowalski (US 5,459,677), Wehlburg,

Greensill, Ozdemir (Applied Spectroscopy 1999), Sum, Despagne or Swierenga. In the patent

Jacobs teaches apparatus and method for detecting patient sample quality, and/or analytes, in the

tip used to aspirate the patient sample liquid and then dispense it onto a slide test element.

Spectrophotometric analysis is done on the liquid while still in the tip, by scanning the tip for

transmittance in a light-tight enclosure, using NIR and adjacent visible radiation, and detecting

the absorbance spectra of the liquid. Much smaller liquid volumes, and no through-the-label

detection, are required, compared to doing the scanning of the liquid in a primary patient

collection container. Figures 1-4 and 13-14 show various embodiments of an instrument having

a slot for placing the sample vessel (a light-tight enclosure defining a cavity sized to receive the

tip while mounted on the probe), a spectrophotometer emitting near infrared and adjacent visible

radiation and generating a signal responsive to portions of the radiation absorbed by any medium

the radiation passes through, passageways defining radiation paths to and from the enclosure

from and to the spectrophotometer, the passageways being constructed to deliver and receive,

respectively, the radiation for transmission through the tip when the tip is in place in the cavity, so that liquid in the tip can be irradiated by the radiation to determine concentration of target substances therein (see claim 1). In particular figures 4A and 4B show cavities having a transverse crass section that is at least in part rectangularly-shaped. Column 6, lines 25-46 teach that the station (82) does not have to be constructed as a solid block with only a cavity for the disposable tip and apertures for the fiber optics. Rather it can be constructed as a slot (115) sized for the pipet (48A) to pass through as shown in figures 4A and 5. Such a slot would allow other sample containing vessels, tubes or tabs to pass therethrough and interact with the light path. Column 6, lines 3-10 teach as analytes at least hemoglobin, lipids, bilirubin (BR), and biliverdin (BV). Other compounds that are substances capable of spectrophotometric detection by its absorption spectra are also taught as possible analytes. The paragraph bridging columns 9-10 teaches a variety of calibration algorithms and derivatives used in the concentration calculations. Columns 10-11 give other examples of calibration algorithms used. Jacobs does not teach that the calibration algorithms were developed on another instrument and transferred to the instrument being used in the analysis.

In the patent Kowalski teaches calibration transfer for analytical instruments. In the background section Kowalski discusses calibration of analytical instruments and notes that calibration models are very powerful at deriving concentration information from spectra. However no two instruments are identical to each other. This creates the problem that the calibration model developed on one instrument cannot be used on another instrument without a significant loss of accuracy. The ideal solution to this is to calibrate each individual instrument, but this is not practical and it would be highly useful to develop a technique to transfer a calibration model from a first or reference instrument to a second or target instrument. A technique for transferring a multivariant calibration model from a reference analytical instrument to a target analytical instrument that may be a different instrument, or the same instrument at a later time. In a "direct" approach, a plurality of transfer samples are selected, and a plurality of measurements are made for each transfer sample using the reference instrument, producing a reference instrument response for each sample. These measurements are repeated for the target instrument, to produce a target instrument response for each transfer sample. One then generates

transfer coefficients capable of performing a multivariate estimation of the reference instrument responses for the transfer samples from the target instrument responses for those samples. The transfer coefficients may then be used to convert a target instrument response for an unknown sample into the equivalent response for the reference instrument. In an important "piecewise" variation, the transfer coefficients comprise a plurality of estimation coefficients for estimating each reference data value from more-than-one but less-than-all target data values. "Classical" and "inverse" transfer techniques are also described, wherein target instrument responses for the transfer samples are combined with reference instrument responses for the full set of calibration samples, to derive a multivariate prediction model for the target instrument.

In the paper Wehlburg teaches a new hybrid algorithm for transferring multivariate quantitative calibrations of intra-vendor near-infrared spectrometers. A new prediction-augmented classical least-squares/partial least-squares (PACLS/PLS) hybrid algorithm is ideally suited for use in transferring multivariate calibrations between spectrometers. Spectral variations such as instrument response differences can be explicitly incorporated into the algorithm through the use of subset sample spectra collected on both spectrometers. Two current calibration transfer methods, subset recalibration and piecewise direct standardization (PDS), also use subset sample spectra to facilitate transfer of calibration. The three methods were applied to the transfer of quantitative multivariate calibration models for near-IR (NIR) data of organic samples containing chlorobenzene, heptane, and toluene between a primary and three secondary spectrometers that were all the same model, called intra-vendor transfer of calibration. The hybrid PACLS/PLS method outperformed subset recalibration and provided predictions equivalent to PDS with additive background correction on the two secondary spectrometers whose instrument drift appeared to be dominated by simple linear baseline variations. One of the secondary spectrometers had complex instrument drift that was captured by repeatedly measuring the spectrum of a single repeat sample. In calculating a transfer function to correct prediction spectra, PDs assumes no instrumental drift on the secondary spectrometer. Therefore, PDS was unable to directly accommodate both the subset samples and the use of a single repeat sample to transfer and maintain a calibration on that secondary instrument. In order to implement the transfer of calibration with PDS in the presence of complex instrument drift,

recalibrated PLS models that included the repeat spectra from the secondary spectrometer were used to predict the spectra transformed by PDS. The importance of correcting for drift on the secondary spectrometer during calibration transfer was illustrated by the improvements in prediction for all three methods vs. using only the instrument response differences derived from the subset sample spectra. When the effects of instrument drift were complex on the secondary spectrometer, the PACLS/PLS hybrid algorithm outperformed both PDs and subset recalibration. Through the explicit incorporation of spectral variations, due to instrument response differences and drift on the secondary spectrometer, the PACLS/PLS algorithm was successful at intra-vendor transfer of calibrations between NIR spectrometers.

In the paper Greensill teaches calibration transfer between PDA-based NIR spectrometers in the NIR assessment of melon soluble solids content. In near-IR (NIR) spectroscopy, the transfer of predictive models between Fourier transform near-IR (FT-NIR) and scanning-grating-based instruments has been accomplished on relatively dry samples (<10% water) using various chemometric techniques-for example, slope and bias correction (SBC), direct standardization (DS), piecewise direct standardization (PDS), orthogonal signal correction (OSC), finite impulse transform (FIR) and wavelet transform (WT), and application of neural networks. In this study, seven well-known techniques [SBC, DS, PDS, double-window PDS (DWPDS), OSC, FIR, and WT], a photometric response correction and wavelength interpolative method, and a model updating method were assessed in terms of root mean square error of prediction (RMSEP) (using Fearn's significance testing) for calibration transfer (standardization) between pairs of spectrometers from a group of four spectrometers for noninvasive prediction of soluble solid content (SSC) of melon fruit. The spectrometers were diffraction grating-based instruments incorporating photodiode array photodetectors (MMS1, Carl Zeiss, Jena, Germany), used with a standard optical geometry of sample, light source, and spectrometer. A modified WT method performed significantly better than all other standardization methods and on a par with model updating.

In the paper Ozdemir teaches multi-instrument calibration with genetic regression in UV-visible spectroscopy. The applicability of genetic regression (GR) to multi-instrument calibration was demonstrated by using several UV-visible spectrophotometers. GR is a

calibration technique that optimizes linear regression using a genetic algorithm (GA). Sample spectra of ternary and quaternary mixtures of the pharmaceuticals furaltadone (Fd), doxycycline (Dx), sulfadiazine (Sd), and trimethoprim (Tm) were collected on four different UV-visible spectrophotometers, including one single-beam diode array and three double-beam dispersive instruments. Hybrid calibration models (HCMs) were generated by combining the data collected on multiple instruments into one calibration model as if they had all been collected on a single instrument. For comparison, single-instrument calibration models were also generated for each instrument. Both HCMs and single-instrument models were tested by using a validation set measured on all four instruments. Results obtained from single-instrument models were comparable with a previous study in which partial least squares (PLS) regression was used for multivariate calibration of these compounds. HCMs for double-instrument cases performed equally well as single-instrument models and slightly worse for the four-instruments models.

In the paper Sum discusses standardization of fiber-optic probes for near-infrared multivariate calibrations. The standardization of Fourier transform near-IR (FT-NIR) spectrometers equipped with fiber-optic probes was studied. FT-NIR spectra of caustic brines for an industrial process were measured on two different instruments. Calibration transfer across the instruments and probes was studied by employing calibration models built on one instrument to predict properties from spectra measured on the other. The transfer was examined by using spectra without and with preprocessing. The preprocessing methods included a Savitzky-Golay (SG) derivative polynomial filter, a procedure based on a finite impulse response (FIR) filter, and a combination of both. In addition to being a preprocessing technique, the FIR filter is also a standardization method that transforms the instrument response function of one instrument to match that of another. The transformation was performed over a moving processing window without the use of transfer standards. Application of the FIR filter to 1st-derivative spectra provided the best multivariate calibration models and led to the successful transfer of calibration across different probes and spectrometers.

In the paper Despagne teaches transfer of calibrations of near-infrared spectra using neural networks. A new approach for multivariate instrument standardization is presented. This approach is based on the use of neural networks (NNs) for modeling spectral differences between

two instruments. In contrast to the piecewise direct standardization (PDS) method to which it is compared, the proposed method builds a single transfer model for all spectral windows. The apparently incompatible requirements for a high number of training objects and a low number of standardization samples are addressed by truncating spectra in finite-size windows and assessing a position index to each window. Each spectral window with the corresponding position index constitutes a training object. No prior background correction is required with this method. Both the proposed method and PDS were applied to some real and simulated data sets, and results were evaluated for reconstruction and subsequent calibration. On the studied data sets, the neural network approach was found to perform at least as well as PDS for both reconstruction and calibration.

In the paper Swierenga presents a comparison of two different approaches toward model transferability in NIR spectroscopy. Recently, efficient methods have become available to transfer a multivariate calibration model from one instrument to another. Two categories can be distinguished: improvement of the robustness of the calibration model by, for example, proper data preprocessing; and adaptation of the calibration model by, for example, (piecewise) direct standardization. In direct standardization, a subset from the calibration set should be measured on both instruments. Usually, however, the calibration samples cannot be measured on both instruments. When data preprocessing is applied to the transfer of multivariate calibration models, there is no need for remeasurement of a subset on both instruments. In this paper, both categories are compared for the determination of the component concentrations in a ternary mixture of methanol, ethanol, and 1-propanol using NIR spectroscopy. The calibration models obtained on one instrument are transferred to other NIR instruments. It has been found that the results of proper data preprocessing are comparable with the results obtained by direct standardization when the models are transferred over three NIR instruments.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the calibration transfer methods of Kowalski, Wehlburg, Greensill, Ozdemir, Sum, Despagne or Swierenga to provide the calibration algorithms used by Jacobs from a primary or reference instrument because of the ability to overcome the problem of variance between instruments taught by at least Kowalski with accuracy that is similar to that that would

have been obtained by performing the calibration on each instrument as taught by Kowalski,

Wehlburg, Greensill, Ozdemir, Sum, Despagne or Swierenga.

6.   Applicant's arguments with respect to the claims have been considered but are moot in

view of the new ground(s) of rejection. The change in the claims has added new matter and

therefore the claims have been newly rejected over that basis. Based on this problem, the claims

are being interpreted as only requiring the slot to have some portion that can be said to have a

rectangularly-shaped transverse cross section. The art related arguments filed November 18,

2009 have been fully considered but they are not persuasive. The new language added to the

independent claims relative to sample slot does not define over the slots shown in figures 4A and

4B of the primary Jacobs reference. Again what the claims and applicant's arguments have

failed to do is clearly claim and or distinguish the claimed the slot from any slot that can receive

a test element for analysis. To that extent the instant claims are clearly obvious in view of the

applied combinations.

7.   Applicant's amendment necessitated the new ground(s) of rejection presented in this

Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

        A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this

final action.

        Any inquiry concerning this communication or earlier communications from the
examiner should be directed to Arlen Soderquist whose telephone number is (571)272-1265.
The examiner can normally be reached on Monday-Thursday and Alternate Fridays.
        If attempts to reach the examiner by telephone are unsuccessful, the examiner's
supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the
organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Arlen Soderquist/
Primary Examiner, Art Unit 1797